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Original article

International Classification of Functioning, Disability and Health Core Set construction in systemic sclerosis and other rheumatic diseases: a EUSTAR initiative

Lesley Ann Saketkoo[1], Reuben Escorpizo[2,3], Kevin J. Keen[4], Kim Fligelstone[5,6] and Oliver Distler[7] on behalf of EUSTAR

Abstract

Objectives. To outline rationale and potential strategies for rheumatology experts to be able to develop disease-specific Core Sets under the framework of the International Classification of Functioning, Disability and Health (ICF). ICF is a universal framework introduced by the World Health Organization (WHO) to describe and quantify the impact and burden on functioning of health conditions associated with impairment/disability.

Methods. A combined effort of the EULAR Scleroderma Clinical Trial and Research and the ICF Research Branch was initiated to develop an ICF language for scleroderma. From our Medline literature review, using the abbreviation and spelled out version of ICF, we assembled approaches and methodological reasoning for steps of core set development.

Results. The ICF can be used for patient care and policy-making, as well as the provision of resources, services and funding. The ICF is used on institutional, regional, national and global levels. Several diseases now have ICF Core Sets. Patients with complex rheumatologic diseases will benefit from a disease-specific ICF Core Set and should be included in all stages of development. ICF Core Set development for rheumatic diseases can be conducted from a number of feasible strategies.

Conclusion. This overview should help to clarify useful processes leading to development of an ICF Core Set, and also provide a platform for expert groups considering such an endeavour.

Key words: scleroderma, systemic sclerosis, functioning, disability, ICF, WHO, health economics.

CLINICAL SCIENCE

[1]Department of Medicine, Louisiana State University Health Sciences Center, Scleroderma and Sarcoidosis Patient Care and Research Center, Section of Rheumatology, New Orleans, LA, USA, [2]ICF Research Branch in cooperation with the WHO Collaborating Centre for the Family of International Classifications in Germany (at DIMDI), Nottwil, Switzerland, [3]Department of Health Sciences and Health Policy, University of Lucerne, Lucerne, Switzerland, [4]Department of Mathematics and Statistics, University of Northern British Columbia, Prince George, Canada, [5]Royal Free Hospital Centre for Rheumatology, Scleroderma Unit, London, UK, [6]The Scleroderma Society, Chichester, UK and [7]Department of Rheumatology, University Hospital Zurich, Zurich, Switzerland.

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Correspondence to: Lesley Ann Saketkoo, Scleroderma and Sarcoidosis Patient Care and Research Center, LSU HSC Department of Medicine, 1542 Tulane Avenue, Room 442, New Orleans, LA 70112, USA. E-mail: ctd.ild@gmail.com

The International Classification of Functioning, Disability and Health

The International Classification of Functioning, Disability and Health (ICF) is a universal framework introduced by the World Health Organization (WHO) to describe and quantify the impact of impairment caused by health conditions on functioning, which may lead to disability. The ICF is a common idiom across diseases, health professionals and policy-makers, which uses a standardized alphanumerical language. The ICF is accepted by national and international health-care and policy-making systems to assess the impact of disease on personal, scientific,

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economic and service levels. It is devised to be a fair representation of disability and impairment of functioning that is consistent and comparable across gender, socioeconomic, geographic, cultural, gender and disease parameters.

The ICF is used or being initiated in some capacity in 71 countries, including Argentina, Australia, France, Germany, Ireland, Italy, Japan, Malawi, Mexico, Netherlands, Sweden, Switzerland and Zimbabwe; 191 WHO member states in 2002 have agreed to adopt ICF for scientific standardization of disability data [1, 2]. Diseases linked to the ICF include RA, AS, IBD, OA, osteoporosis, back pain, diabetes, ischaemic heart disease, chronic obstructive pulmonary disease, obesity, stroke, multiple sclerosis, spinal cord injury, traumatic brain injury, Guillain–Barre, myasthenia gravis, sleep disorders, depression, chronic widespread pain, breast cancer and head and neck cancer.

The ICF is based on the biopsychosocial model that takes into account the impact of disease beyond the traditional model of health in terms of the pathophysiological biological model of disease within the biological confines of the patient [3]. The biopsychosocial model describes the health experience of the whole person in relation to their disease state, the effects of disease on the body and the impact of disease on important aspects of living in society and on the patient's interactions with their environment. It departs from the traditional biological model of health, in that beyond the concepts of how a disease changes the body's structure and the body's ability to function on a molecular, histological or anatomical level, the biopsychosocial model of health recognizes that intrinsic to the measurement of disease is the environment within which the patient operates. It recognizes that real-life operationalizes impairment, limitations or restrictions. It is at this juncture that disability or functioning is truly defined. Additionally, just as health status effects the host's interaction with their environment, so the environment affects the health outcomes and status of the host. A good example of this would be a severe mobility impairment resulting in complete reliance on a wheelchair—restricting one's ability to participate in work if there are no accommodations for entry into the workplace. However, a positive life effect on remunerative and self-esteem aspects would result if the environment facilitated entry into the workplace. This positive life effect is likely to have an overall positive effect on the individual's health and participation in society. The ICF strives to capture and quantify the burden associated with the disease in all the essential functioning aspects of a patient's life.

Implications for rheumatic diseases

Functioning is an essential consideration in chronic illness. The development of disease-specific core sets for complex rheumatic diseases that are based in the language of the ICF potentially ensures fair representation of the burden of these diseases on global and regional stages. If core set development is conducted by the disease experts themselves—meaning patients as well as physicians, rehabilitation specialists and specialist nurses with a dedicated expertise in the particular disease—one would expect a more accurate ICF language for a specific disease. The ability to describe the burden of disease within the context of the ICF creates a quantifiable argument for funding and allocation of resources in regard to research, provision of patient services as well as having potential effects on government and insurance policies that affect patients with chronic rheumatic diseases.

Mechanics of ICF

A note of clarification: the ICF is different from the WHO International Classification of Diseases, which names the disease or condition (for example, the International Classification of Diseases code for RA is 714.0). The ICF describes the type and degree of various functioning impairments, limitations and restrictions related to or associated with a condition.

Parts

The ICF is broken down into two main parts (Fig. 1) that have several components. There are 1454 classifications housed hierarchically under these components.

The first part (i.e. functioning) is composed of three components: body structure (s), which is related to anatomy; body function (b), which refers to the physiological and psychological functions of the body; and activities and participation (d), whereby activities are tasks or actions with a goal and participation is activity placed within contextual meaning such as social, family, work, etc.

The second part is currently composed of two components: environmental factors (e), which allows for recording the positive or negative influence of the environment (e.g. assistive devices, access to care, climate, etc.) on functioning; and personal factors (pf), which are personal characteristics of the individual. These are not yet classified (i.e. coded) in the ICF at this time.

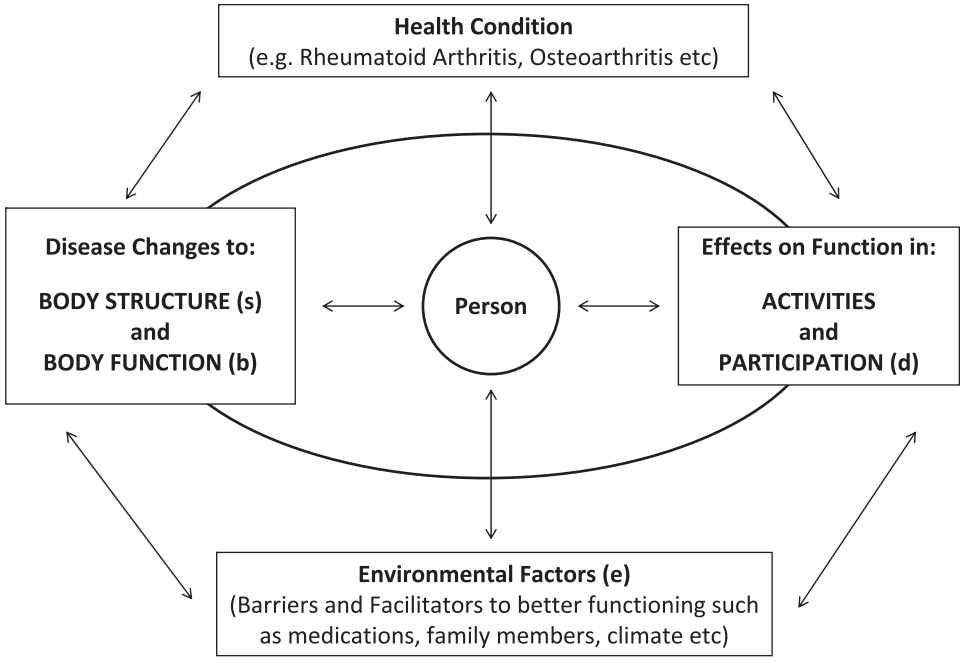
Classification hierarchy

At the first level of classification are chapters, followed by second, third and fourth levels (Table 1), when available.

Chapters are the broadest headings relevant to a component. The chapters pertaining to body structure (s) and body function (b) relate to body systems. The chapters for body structure and body function are parallel to each other for ease of use. For example, chapter 6 for components s6 and b6 relates to the genitourinary and reproductive systems and functions.

Under the chapters come the second level of classifications that comprise subheadings that deconstruct a chapter to its basic elements. Most ICF Core Sets are developed to this second level of classification. However, there is no rule as such. Beneath the second level is the third level of classifications that confers detail to the second-level manifestations. The third level attempts to capture a further level of detail of the patient experience. An example for dysphagia would be b51052, where b5 is the body functions chapter, Functions of the digestive, metabolic and endocrine systems; b510 is the second-level classification of Ingestion functions; b5105 is

Fig. 1 Interactions between domains of ICF in relation to the health condition.



Adapted from the ICF's Towards a Common Language of Functioning, Disability and Health (Geneva, Switzerland: WHO, 2002).

Table 1 A hierarchy of visual impairment

Level	Example	Coding
Chapter	Chapter 2: Sensory functions and pain	b2
Second level	Seeing functions	b210
Third level	Quality of vision	b2102
Fourth level	Colour vision	b21021

Reproduced from the ICF's Towards a Common Language of Functioning, Disability and Health (Geneva, Switzerland: WHO, 2002), http://www.who.int/classifications/icf/training/icfbeginnersguide.pdf (30 May 2012, date last accessed), with permission.

the third level of Swallowing and b51052 is the more detailed classification of Esophageal swallowing. One can interact with the ICF hierarchy at http://apps.who.int/classifications/icfbrowser/.

Recording impairment

Regarding utility, the ICF framework is flexible. It provides a vehicle for answering a wide range of questions involving clinical use, research and policy-making that can be easily understood among professional disciplines. The ICF uses a five-point qualifier for the scale of impairment in addition to classifications that comfortably and meaningfully translate visual analogue or percentage scales. Such a five-point scale is well suited also to gauge change over time for purposes of research and clinical care. For example, severe impairment of oesophageal swallowing can be described as b51052.4, where 4 indicates a level of complete impairment on a scale of 0–4 (0 = no impairment, 1 = mild impairment, 2 = moderate impairment, 3 = severe impairment, 4 = complete impairment).

ICF Core Sets

It has been generally accepted for diseases (or groups of similar disorders) that it is worthwhile to collate a comprehensive core set of ICF categories for use in multidisciplinary assessments of patients. Although most ICF Core Sets develop categories only to the second level of classification, there is no rule for this. Comprehensive core sets are usually composed of a large number of items and so are not always feasible for daily clinical use. For this reason, there is often a brief core set generated, which is an abbreviated list of the minimum relevant ICF categories for use in a targeted clinical setting or research setting [4]. A brief ICF Core Set is based on the larger comprehensive ICF Core Set. Core sets have in the past been derived in a

multi-step approach, which, in the earlier history of core set development, did not incorporate patients' insights [5].

Careful consideration in planning the core set methodology ensures that appropriate structure and strategies are used for the particular disease in question. In the preliminary steps, it is important to obtain the broadest collection of disease descriptors before proceeding with strategies to reduce the collection into the comprehensive and brief core sets:

$$\text{Item collection} \gg \text{Continued item collection with opportunity for item reduction} \gg \text{Item reduction}$$

The goals of methodology and examples of strategies that have been used to accomplish core set development are outlined as follows.

Item collection

The development of comprehensive core sets usually begins with exercises to identify qualities and ICF categories related to the disease in question. This involves combinations of methods to collect a group of qualities associated with a disease. In the early history of core set development [6], central to this collection was a literature review to identify relevant outcome measures, item-generating discussions and Delphi exercises (see below) with health-care professionals, as well as application of a formal ICF checklist [7, 8], or a review of medical data in a cross-sectional convenience sample of patients [9] for generating categories that were typical, relevant and frequent in patients with a specific disease. This item collection (authors' term) phase was later modified by some efforts to include patients in focus groups and/or Delphi exercises [10] as well as augmenting the role of allied health professionals [11]. This list of qualities that is generated is then linked to the ICF usually by two reviewers who are health professionals and familiar with ICF linkage rules [12].

Content and face validation

Traditionally the core set has been selected from this collection of ICF codes (with their descriptors) by health professionals (16–30 participants), using group consensus exercises to select codes that are relevant and typical for the disease. The types of consensus techniques for these processes are typically not described in the literature other than noting that some efforts included plenary and break-out sessions. The codes may also undergo a similar process through a Delphi consensus process (using a three-step voting survey) that most commonly includes health professionals. The Delphi exercises have traditionally used a two-point Likert scale (yes/no) anchored in relevant or typical of the health condition. Delphi exercises usually include the ability to add items that the participant perceives are missing. Face and content validity may also be sought from specific groups (patients, nurses, rehabilitation therapists or physicians) [11, 13] that may possess a specific perspective on the disease or may have been missed in the earlier processes of the core set's development. This is most commonly done using a Delphi exercise.

Construct validation

Testing of the core set in real-life situations provides insight into which components of the core set have construct validity. Cross-sectional studies can assist in this and might use any number of strategies: several serial surveys to track patient-reported perspectives that assess the disease state over time [14], or application of the core set in clinical settings, such as rehabilitation facilities, out-patient health centres, etc., to test the real-life utility of the core set. This process may ultimately reveal the need for further item reduction or augmentation.

ICF Core Set for RA: an example

The core set development for RA [5, 15] was one of the first 12 diseases undertaken in an *en masse* effort that began with a three-pronged strategy in the collection of qualities: (i) a Delphi exercise including health professionals whose level of expertise in RA was not described; (ii) a literature review of clinical trials in RA published from 1991 to 2000 to identify outcome measures relevant to RA; and (iii) data collection from cross-sectional convenience samples of RA patients by chart review and interview were applied against the ICF checklist of 125 ICF categories identified as being important in chronic diseases in order to assess which categories are relevant to RA. The items from each step were linked to the ICF by two reviewers. From this, a set of 530 ICF categories were generated at the second, third and fourth levels.

From here, a comprehensive RA core set of 96 categories on the second, third and fourth levels was decided upon with an undescribed formal decision-making process employing 17 experts not including patients. The level of expertise in RA was not reported, with half of the physicians being non-rheumatologists, but was described as at least a specialization in physical medicine, with one each of a nurse, an occupational therapist and a physiotherapist, with conflicting information regarding the number of countries represented: both 8 and 12 countries are stated. At the same meeting, experts voted, and items receiving a 50% majority were included in the brief RA core set that yielded 39 second-level categories. The comprehensive RA Core Set was then validated from a nurse's perspective and then by physicians in two separate Delphi exercises [11, 13].

The ICF Core Sets for RA has not been validated against commonly used measures in RA, such as the HAQ; however, Core Sets have been compared with regard to the collection of concepts (or ICF categories) held within validated and commonly used outcome measures [16]. Developing new outcome measures to replace currently used measures is not the purpose of an ICF Core Set. Rather an ICF Core Set should present, at a minimum, the disease experience and all relevant areas of disability (e.g. interference with engagement in life areas). In so doing, the ICF Core Set (due to its broad attempt to collect items) is bound to contain important disease concepts not contained within the most commonly used measures. If, over time, it is perceived that categories not currently reflected within validated

instruments prove to be important to patients or demonstrate high discriminatory properties, it makes sense to consider modification of currently used measures or the introduction of new measures. Although the process of ICF Core Set development may provide a vehicle to identify areas of omission in a current assembly of outcome measures (please see the section on Health Index Development), a Core Set is not intended to replace validated instruments. ICF categories tend to be broad or lack granularity in description, and as such may provide a practical approach that is useful where the detail of instruments such as HAQ or the Short Form-36 may not be helpful in certain settings or have an incomplete description of the disease experience.

Health index development

One of the more intricate strategies exploring the use of ICF in rheumatic disease is an effort in progress for AS [14, 17]. Current outcome measures for AS were perceived to be insufficient in the assessment of disease activity, which inspired these experts (with patient partners) to push beyond the development of core sets and strive to develop a health index in AS using the ICF. This effort is intended to result in a new instrument that will comprise both validated AS assessment methods as well as previously unrecognized components of the AS health experience.

Limitations of the ICF

Unresolved limitations of the ICF exist. The ICF is a broad description of disability and functioning and therefore may be unable to correlate well with the very specific items and interrelated concepts of commonly used measures in specific diseases. Yet, the very specific measures that are used may not be congruent with what is needed in disability data to quantify the true impact of an illness across broad categories in such an accessible way. Additionally, though the ICF provides significant utility in systems (e.g. health information technology, electronic health records) that have adopted the framework, it has limited utility in systems that have not pro-actively adopted it. True adoption requires training and familiarity with the ICF. In addition to the limitation to broad concepts of functioning, the ICF categories are discrete and do not interrelate or form associations in a straightforward manner with other categories. For example, the cause of one's inability to comb one's hair is not discernible from muscle weakness, painful arthritis or breathlessness in a patient with anti-synthetase syndrome, in which muscle, joint and lung involvement are all potential disease manifestations.

Although there has been a commitment by the WHO member states to incorporate the ICF as a scientific basis and platform through which disability data will be collected, it is currently used by 71 WHO member countries, which is less than half of the WHO assembly that agreed to adopt the ICF framework. However, that might be considered significant enough to be worthwhile [2]. But this initial enthusiasm to adopt without subsequent initiation may speak to the lack of either preparedness, ease or resources for implementation.

EUSTAR initiative to develop an ICF Core Set for SSc

The EULAR Scleroderma Clinical Trial and Research (EUSTAR) has emerged from an international SSc registry that has precipitated important key concepts to our current understanding of SSc into a forum and network for many different research activities in SSc with the potential for improved health outcomes for patients with SSc. For the ICF approach described herein, EUSTAR provides the framework for access to international medical and health experts, distribution of the final products as well as potential examination of the identified ICF categories to furthering SSc subgroup identification.

Planned steps towards the development of an ICF Core Set for SSc are as follows:

(i) Gain support and involvement of key SSc patients and scientific organizations.
(ii) Medical and Patient Expert Initial Data Collection—Focus Groups:
  (a) Using both open-ended and task-centred strategies to elicit information.
  (b) Broad international representation.
  (c) Broad patient expert inclusion reflecting the spectrum of disease involvement, severity and stage.
  (d) Medical experts include physicians, physiotherapists, occupational therapist, specialty nurses and social workers with clearly defined and recognized expertise in SSc.
  (e) Medical expert involvement must include representation of focal expertise in SSc manifestations such as RP, ulcers, wound care, cardiac manifestations, pulmonary hypertension, pulmonary fibrosis, musculoskeletal, sexual function and health-related quality of life.
(iii) Linkage of instruments validated in SSc:
  (a) Through systematic literature review, identify all instruments validated at any level in SSc.
  (b) Deconstruct each item of each instrument into its most basic concepts per linking rules [12].
  (c) Linkage of deconstructed items of each instrument by two health professionals proficient in ICF (one a physiotherapist and another a rheumatologist with expertise in SSc).
  (d) Interlinker agreement must be $>70\%$ concordance; otherwise a third linker is introduced.
(iv) Pooling of data from focus groups and instruments.
(v) Item reduction and content validation:
  (a) Online survey is to be distributed in several languages for medical and patient experts with a Likert scale anchored in whether the item is important or typical to the SSc experience. The survey will have the ability to provide any aspects that the participant feels might be missing.
  (b) Plenary and small group evaluations with medical and patient experts of post-survey items is to be identified in both the Comprehensive and Brief Core Sets.

(vi) Report of the Comprehensive and Brief Core Sets.
(vii) Construct validation via the following strategies:
  (a) Serial observation using the Core Set in a clinical setting.
  (b) Serial e-mail surveys to patients to assess perceived changes over time.

The aforementioned construct validation strategies are planned for assessment on a five-point scale (no impairment to complete impairment), with like items correlated against commonly used instruments.

The project leaders are keenly aware of issues concerning the complexity and multi-organ system nature of SSc as being novel to the ICF. We are committed to remaining receptive to and accommodating an end-structure that will ensure optimal utility. A key challenge will be in managing efficiently an atypically high number of identified categories. This is likely to require unique approaches. For example, SSc may require several domain-based Core Sets to ensure high utility and broad application. Another predicted challenge, which also may be answered by an organ-based Core Set, is that the ICF currently does not facilitate interrelationships of categories. For example, anxiety that may be the result of dealing with the stress of incontinence will appear as two distinct unassociated categories without an association that would tie the two together such that if the incontinence were not a prominent feature, anxiety might potentially also recede.

Points to consider for ICF Core Set development in SSc and other rheumatic diseases

ICF Core Sets for RA, osteoporosis, OA, chronic widespread pain and low back pain were initiated in the first group of 12 chronic diseases. These core sets were developed in an *en masse* effort [5]. Although these initiatives were productive and an important step forward, there are many more complex diseases that require accurate ICF representation. For example, there have not been core sets developed for complex multi-organ system diseases such as vasculitis or SSc.

EUSTAR and the ICF Research Branch of the WHO Collaboration Centre of the Family of International Classifications in Germany (DIMDI) are working towards the development of an ICF language for systemic sclerosis [18]. Previous papers describing the process of ICF development of core sets have provided results of the development, but somewhat limited details of the process itself. However, we would like to emphasize the importance of a pre-defined methodology, clearly stated validated consensus techniques and clarification of the objectives behind varied methods that have lead to core set development. This would empower the selection or development of unique strategies that are appropriate for ICF Core Set development for future diseases.

Early core set projects engaged mostly physicians and the resulting publications do not specify the degree of expertise for a particular disease. We feel that ICF Core Set development of complex diseases needs careful attention beyond general specialists, but rather subspecialists with a dedicated expertise in the disease in question. For example, it would not be enough to engage general rheumatologists, general rehabilitation experts or nurses in scleroderma ICF Core Set development. A complex disease such as SSc deserves the attention of sclerodermologists, i.e. health care professionals with demonstrated expertise in scleroderma. These important details should be clearly stated in publications.

In rheumatic diseases, it is important to include patients in the processes leading to ICF Core Set development. If patients are included, aspects of the health experience often overlooked by health care professionals are likely to be identified [19–21]. Therefore the strength of the process is enhanced by including patient experts at each validation and decision-making step. We advocate that at least one patient expert contribute to the design and implementation of the methodology [18]. Along the same vein, there should be as equal representation as possible of patients, rehabilitation specialists, specialist nurses and physicians in each step of the process supported by international and cultural diversity.

In summary, the development of ICF Core Sets for rheumatic diseases is important for patient care and patient advocacy so as to ensure fair representation and allocation of resources. Disease-specific ICF Core Set development for complex rheumatic diseases is a tangible and practicable endeavour that is best informed by true experts of the disease in question, namely patients, rehabilitation and nurse specialists and physicians. We anticipate that the challenges faced and the model presented in the development of an ICF Core Set for SSc will be useful in the development of ICF Core Sets for other complex multi-organ system diseases, inclusive of vasculitis and SLE.

Rheumatology key messages

- Multi-level functioning in chronic illnesses, including complex rheumatic diseases, is important in health-care delivery.
- The WHO's ICF standardizes disability data for use at individual, institutional, national and international levels.
- ICF Core Set development for rheumatic diseases is feasible and can be conducted by several strategies.

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